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DEC 18 2001

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David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No.5,194,247 was filed on February 7, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, SOLAGE® (Mequinol), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. SOLAGE® has two active ingredients, but only the active ingredient that was not previously approved is relevant to the application for patent term extension. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Charles J. Zeller
Bristol-Myers Squibb Company
2 Blachley Road
Stamford CT 06922

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